COUNT I
STRICT PRODUCT LIABILITY
DEFECTIVE DESIGN

118. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

119. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the Diet Drugs that were defective and unreasonably dangerous to consumers, including Plaintiffs.

120. At all times material hereto, the Diet Drugs which were researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiffs, without substantial change in the condition in which they were sold.

121. At all times material hereto, the Diet Drugs were in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Diet Drugs contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of the drug;
b. When placed in the stream of commerce, Diet Drugs were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with obesity and/or weight loss;
c. Diet Drugs were insufficiently tested;
d. The intended use of the drugs caused harmful side effects which outweighed any potential utility; and
e. Diet Drugs were not safe for its intended use as a weight loss drug.

122. But for the aforementioned defective and unreasonably dangerous conditions, the Diet Drugs would not have been prescribed to Plaintiffs, Plaintiffs would not have ingested the drugs, and Plaintiffs would not have sustained the injuries alleged herein.

123. As a direct and legal result of the defective condition of the Diet Drugs, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other related injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT II
STRICT PRODUCT LIABILITY
FAILURE TO WARN

124. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

125. Diet Drugs were defective and unreasonably dangerous when it left the possession of Defendants in that Diet Drugs contained warnings which were misleading regarding the purported benefits associated with the drug and were inadequate and insufficient to alert physicians and consumers, such as Plaintiffs, to the dangerous risks and reactions associated with the drugs, including, but not limited to, pulmonary hypertension, heart valve disorders, and other serious and life threatening side affects, especially since any weight loss experienced was transitory. Plaintiffs' injuries and losses are continuing in nature.

126. The physicians prescribed the Diet Drugs to Plaintiffs for the intended purpose.

127. Neither the prescribing physicians nor Plaintiffs could have discovered any defect in the drug through the exercise of reasonable care.

128. Defendants are held to the level of knowledge of an expert in the field.

129. The prescribing physicians did not have substantially the same knowledge as an adequate warning from the manufacturer or distributor should have communicated to the prescribing physicians.

130. The warnings that were given by Defendants to the prescribing physicians were not adequate, accurate, or clear, and were ambiguous.

131. The limited warnings which were provided to the doctors were inappropriately placed in the fine print of the materials provided to the prescribing physicians, and Defendants failed to display those warnings prominently enough such that prescribing physicians and the consuming public would appreciate the true risks of severe and life threatening complications which had been reported in association with Diet Drugs, including, but not limited to, the pulmonary hypertension and VHD.

132. Defendants had a continuing duty to warn the prescribing physicians and Plaintiffs of the dangers associated with the Diet Drugs.

133. As a direct and legal result of Defendants' failure to warn, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT III

NEGLIGENCE

134. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

135. Defendants directly or indirectly, negligently and/or defectively made, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the Diet Drugs throughout the United States.

136. At all times material hereto, Defendants had a duty to Plaintiffs to exercise reasonable care in the researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling of Diet Drugs.

137. Defendants breached that duty and was negligent in its actions and omissions toward Plaintiffs and their prescribing physicians in ways which include, but are not limited to, the following:

a. Failure to include adequate warnings with the drugs that would alert physicians to the potential risks and serious side affects of the drug;
b. Failure to adequately and properly test the drug before placing the drugs on the market;
c. Failure to conduct sufficient testing of the drugs which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, pulmonary hypertension and heart valve disorders;
d. Failure to adequately warn Plaintiffs' prescribing physicians that use of the drugs should be accompanied by a professional examination and regularly scheduled follow-up examinations so that pulmonary hypertension, heart valve disorders and other serious side effects could be avoided or detected early;
e. Failure to adequately warn Plaintiffs' prescribing physicians that use of the drugs carried a risk of pulmonary hypertension, VHD, and other serious side effects;
f. Failure to adequately warn Plaintiffs' prescribing physicians that use of the drugs carried a risk of temporary or permanent disability due to pulmonary hypertension, VHD, and other serious side effects

g. Failure to warn Plaintiffs' prescribing physicians that use of the drug carried a risk that heart surgery might become necessary to repair or replace heart valves damaged by the drug;
h. Failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks of pulmonary and/or VHD and/or cardiovascular injury from the use of the drug;
i. Failure to adequately warn Plaintiffs' prescribing physicians that the drug should not be prescribed for a long period of time or for use in conjunction with other weight loss drugs;
j. Failure to warn the prescribing doctors that the use of the drug should be limited to those who specialized in the treatment of obesity;
k. Failure to warn Plaintiffs' prescribing doctors that use of the drug should be limited to the morbidly obese and not used for cosmetic loss of weight;
l. Failure to warn Plaintiffs' prescribing doctors that the drug would not substantially reduce weight or reduce weight for a long period of time;
m. Failure to warn Plaintiffs' prescribing doctors that the use of the drug had not been properly studied as to safety in animals or humans; and
n. Failure to display the warnings that were provided in a manner which would properly alert the prescribing doctors as to the seriousness of the adverse events which had been reported in association with the drug.

138. Defendants knew or should have known that Diet Drugs caused unreasonably dangerous risks and serious side effects of which Plaintiffs and the prescribing physicians would not be aware.

139. But for Defendants' negligent conduct as described herein, Plaintiffs' prescribing physicians would have never prescribed Diet Drugs to Plaintiffs, Plaintiffs would not have ingested Diet Drugs and Plaintiffs would not have suffered harm from ingesting Diet Drugs.

140. As a direct and legal result of the negligence of Defendants, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries; disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT IV
FRAUDULENT/NEGLIGENT MISREPRESENTATION

141. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

142. Defendants, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of Diet Drugs owed a duty to provide complete and accurate information regarding the drug to Plaintiffs, their physicians, and anyone else Defendants knew or should have known would ingest or prescribe the drug.

143. Defendants misrepresented material facts regarding the safety and efficacy the diet drug, and failed to inform Plaintiffs, the public and Plaintiffs' prescribing physicians these material facts.

144. Defendants fraudulently and/or negligently misrepresented to Plaintiffs, Plaintiffs' physicians, the FDA, and the general public that Diet Drugs were safe and effective, that the benefits of taking the drug outweighed any risks, and/or fraudulently and/or negligently misrepresented and concealed safety and effectiveness information regarding the product, including but not limited to the drug's propensity to cause serious physical harm. The continuous and ongoing course of action constituting fraudulent and/or negligent misrepresentation on Plaintiffs started as early as 1992, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

145. Diet Drugs were in fact unsafe and the use of Diet Drugs posed a risk of injury and death which outweighed the purported benefits of its use, such that injury was in fact caused to Plaintiffs and others.

146. Defendants made fraudulent and/or negligent misrepresentations regarding adverse information at a time when it knew, or should have known, that Diet Drugs had defects, dangers, and characteristics that were other than what Defendants had represented to the prescribing doctors or other dispensing entities, the FDA, and the consuming public, including Plaintiffs. Specifically, Defendants misrepresented the following:

a. It was dangerous to prescribe the Diet Drugs;
b. Diet Drugs were not intended for cosmetic weight-loss;
c. The Diet Drugs carried risks of serious adverse effects;
d. After discontinuing use, most users of the Diet Drugs would regain any weight lost as a result of its use;
e. There had been insufficient studies regarding the safety and efficacy of the Diet Drugs for use in treating weight loss;
f. That prior studies, research, reports and/or testing had been conducted linking the use of the drug or similar drugs, to serious adverse reactions, including, but not limited to, pulmonary hypertension, and VHD;
g. The fact Defendants knew, or should have known of twenty-five (25) cases of heart-valve damage reported in Belgium and/or elsewhere in Europe related to the drug or similar drugs;
h. The fact that Defendants knew or should have known of the greatly increased risk of developing pulmonary hypertension, as well as a great number of reports of the disorder related to the drugs' use;
i. the known number of cases reported to Defendants of persons who had contracted pulmonary hypertension after ingesting Diet Drugs;
j. The results of studies on animals, which revealed marked abnormalities in the cardiac and/or pulmonary tissues of these animals following diet drug ingestion;
k. The safety and efficacy of Diet Drugs in labeling, advertising, product inserts, and other materials;
l. The number of deaths that had been associated with Diet Drugs, the number of cases of heart valve damage associated with the drug, the number of cases of pulmonary hypertension associated with the drug, and the fact that the drug had been associated with pulmonary hypertension and VHD;
m. That the Diet Drugs were less effective than a placebo in achieving their intended purpose; and
n. The nature and extent of any beneficial health effect the Diet Drugs would provide the user.

147. The misrepresentations alleged above were perpetuated directly and indirectly by the Defendants.

148. The fraudulent and/or negligent misrepresentations of Defendants took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information regarding the products while having a duty to disclose to Plaintiffs and others such information.

149. Defendants knew or should have known that these representations were misleading at the time they were made or omitted, and made the representations with the intent or purpose that Plaintiffs and Plaintiffs' physicians would rely on them, leading to the use of the Diet Drugs by Plaintiffs.

150. At the time of Defendants' fraudulent and/or negligent misrepresentations, Plaintiffs and Plaintiffs' physicians were unaware of the inaccuracy of the statements being made and believed them to be true.

151. Plaintiffs' physicians and Plaintiffs justifiably relied on and were induced by the misrepresentations and relied on the absence of adverse safety information in the prescription and ingestion of the Diet Drugs.

152. Defendants had a post-sale duty to warn Plaintiffs and or Plaintiffs' physicians about the potential risks and complications associated with Diet Drugs in a timely manner.

153. The misrepresentations by Defendants constitute a continuing tort.

154. Defendants made the statements and/or omissions with the intention that Plaintiffs, Plaintiffs' prescribing physicians or other dispensing entities and the consuming public would rely on such or the absence of such information in selecting Diet Drugs as a treatment for weight loss.

155. As a direct and legal result of the fraudulent and/or negligent misrepresentations of Defendants, Plaintiffs have sustained serious and permanent injuries including, but not limited to,

injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendants for damages, as well as all costs of this action.

COUNT V
FRAUDULENT CONCEALMENT
(AGAINST DEFENDANT INTERNEURON ONLY)

156. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

157. To date, even in light of the existence of overwhelming scientific proof in the form of countless epidemiologic studies and other tests and/or studies, Defendant, Interneuron, still claims that "[b]ased on the results of studies to date, the incidence of cardiac valve abnormalities has been shown to be less than that suggested by the original FDA preliminary analysis. In general, these studies have shown either no or relatively small differences, although in some cases statistically significant, between the incidence of cardiac valve abnormalities, as defined by the FDA, among patients who took Redux and placebo-treated patients and that the incidence of such abnormalities among Redux patients was less than previously reported estimate."

158. Furthermore, in response to law suits which have been brought against Interneuron by shareholders claiming that Interneuron misled shareholders and committed securities fraud relating to its actions associated with the approval and subsequent marketing of Redux, Interneuron has

plainly yet fallaciously stated that it did not conceal known risks regarding Redux, and it has uniformly denied the causal link between Redux ingestion and the injuries referenced herein.

159. Interneuron, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of Redux owed a duty to provide complete and accurate information regarding the drug to Plaintiffs, their physicians, and anyone else it knew or should have known would ingest or prescribe Redux.

160. Interneuron has misrepresented material facts regarding the safety and efficacy of the Diet Drugs, and failed to inform Plaintiffs, the public and Plaintiffs' prescribing physicians these material facts, to this day.

161. The continuous and ongoing course of action constituting fraudulent concealment on Plaintiffs started as early as 1992, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

162. Interneuron actively concealed adverse information at a time when it knew, or should have known, that Redux had defects, dangers, and characteristics that were other than what it knew or should have known existed regarding the dangerous side effects associated with Redux.

163. The active concealment alleged were perpetuated directly and indirectly by Interneuron, and took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, and a campaign of misinformation intended to convince Plaintiffs, Plaintiffs prescribing physicians, and the public that Redux is not associated with VHD or PH, and is in fact a safe and effective product.

164. Interneuron knew or should have known that these representations were false or misleading at the time they were made or omitted or concealed, and made the representations with the intent or

purpose that Plaintiffs and Plaintiffs' physicians would rely on them, leading to the use of Redux by Plaintiffs, and with the specific intention that Plaintiffs rely on such misrepresentations and concealment by delaying in obtaining appropriate medical care and monitoring, in discovering their injuries associated with the use of Redux, and in discovering that such injuries were caused by the acts and omissions of Interneuron.

165. Plaintiffs and Plaintiffs' physicians had no knowledge of the information concealed and suppressed by Defendants and were unaware of the inaccuracy of any statements being made and believed them to be true.

166. Plaintiffs and Plaintiffs' physicians justifiably relied on and were induced by Interneuron's active concealment and relied on such actions, statements, and omissions.

167. Interneuron had a post-sale duty to warn Plaintiffs and or Plaintiffs' physicians about the potential risks and complications associated with Redux in a timely manner.

168. The misrepresentations and active concealment by Interneuron constitutes a continuing tort.

169. Such concealment has served to toll any applicable statute of limitations that applies to Plaintiffs' claims against Interneuron. As a direct result of the concealment, and their justified reliance thereon, Plaintiffs did not and could not have discovered their injuries caused by the ingestion of Redux, until they received an echocardiogram which indicated the presence of FDA positive valvular heart disease and did not and could not have discovered that such injury was caused by the acts and omissions of Interneuron or their ingestion of Redux..

170. As a direct and legal result of the fraudulent concealment by Interneuron, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of

capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against Defendant Interneuron for damages, as well as all costs of this action.

COUNT VI
G.L. c. 93A UNFAIR AND DECEPTIVE PRACTICES
(AGAINST DEFENDANTS INTERNEURON AND BOEHRINGER ONLY)

171. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

172. Defendants Interneuron and Boehringer were at all times material hereto engaged in the conduct of trade and commerce throughout the United States including the Commonwealth of Massachusetts and the States within which Plaintiffs were prescribed and ingested Redux.

173. Defendants Interneuron and Boehringer engaged in trade and commerce with respect to the design, manufacture, approval, marketing, promotion, distribution and sale of Redux, a defective product, which was unfit for its intended use, and which had risks that substantially outweighed any benefits.

174. Defendants Interneuron and Boehringer, in furtherance of their business of trade and commerce, did knowingly and willfully fail to disclose to Plaintiffs individually and by and through their physicians information about the risks associated with the ingestion of Redux.

175. Interneuron and Boehringer made misleading statements and failed to disclose information to Plaintiffs individually and by and through their physicians concerning Redux in its marketing, promotion, distribution, and sale.

176. Interneuron and Boehringer knew the facts concerning Redux were material to Plaintiffs and their physicians in assessing the safety of Redux. Defendants also knew that withholding this information would place Plaintiffs at further risk of injury.

177. Interneuron and Boehringer made these misrepresentations and failed to disclose material facts for the purpose of inducing Plaintiffs to purchase and ingest Redux.

178. Plaintiffs relied to their detriment on Interneuron's and Boehringer's representations that Redux was an effective and relatively risk free diet drug.

179. As a result of their reliance and as a direct and proximate cause of Interneuron's and Boehringer's willful or knowing unfair or deceptive acts or practices in violation of G.L. c. 93A, § 2, Plaintiffs have sustained serious and permanent injuries including, but not limited to, injuries to the heart, pulmonary system and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiffs' injuries and losses are continuing in nature.

180. Interneuron's and Boehringer's violation of G.L. c. 93A, § 2 entitles Plaintiffs individually to an award of actual damages and reasonable attorney's fees and costs incurred in connection with said action.

181. Interneuron's and Boehringer's actions which resulted in their failure to provide accurate and sufficient information about the true risks of pulmonary hypertension, VHD and other injuries constitute unfair and deceptive acts and practices as defined in G.L. c. 93A.

182. Defendants knowingly and willfully engaged in these unfair and deceptive acts and practices in violation of G.L. c. 93A, § 2, entitling Plaintiffs to an award of up to treble but not less than double damages against Defendants Interneuron and Boehringer.

183. Defendants' unfair and deceptive acts and practices occurred primarily and substantially within Massachusetts because, among other things: Defendants' principal place of business is in Lexington, Massachusetts and at all relevant times Defendants and its officials were conducting business in Massachusetts when they engaged in unfair and deceptive acts and practices; and Defendants committed said unfair and deceptive acts in marketing, promoting, packaging, labeling, compounding, distributing, detailing, and/or selling Redux to the public, including Plaintiffs.

184. Plaintiffs have substantially complied and/or will comply with all requirements of G.L. c. 93A , § 9.

WHEREFORE, Plaintiffs demand judgment against Defendants Interneuron and Boehringer for damages, including actual damages, which Plaintiffs request to be trebled or doubled by the Court, as well as reasonable attorney's fees and costs incurred in connection with this action, and any other relief this Court deems proper.

PLAINTIFFS CLAIM A TRIAL BY JURY.

Edward J. Barshak, (BBO No. 032040)
Michael S. Appel, (BBO No. 543898)
Sugarman, Rogers, Barshak & Cohen, P.C.
101 Merrimac Street, 9th Floor
Boston, MA 02114
(617) 227-3030

Samuel W. Lanham, Jr.
Cuddy & Lanham, P.A.
470 Evergreen Woods
Bangor, ME 04401
(207) 942-2898

Neil D. Overholtz
Aylstock, Witkin & Sasser, P.L.C.
55 Baybridge Drive
P.O. Box 1147
Gulf Breeze, FL 32562-1147
(850) 916-7450

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